

Hospira, Inc

June 2006

Original 510(k) Premarket Notification
OPTICATH® Central Venous Oximetry Catheter**510(k) SUMMARY****OCT - 5 2006**

- 1. Submitted by:** Hospira, Inc.
D-389 Bldg. H2
275 N. Field Drive
Lake Forest, IL 60045
- Contact: Nichol R. Wilding
Phone: (224) 212-5270
Fax: (224) 212-5401
- 2. Date Prepared:** June 5, 2006
- 3. Name/Classification of Device:** Fiberoptic Oximetry Catheter, Class II
78 DQE – 21 CFR Parts 870.1230
- 4. Trade Name of Proposed Device:** OPTICATH® Central Venous Oximetry Catheter
- 5. Predicate Devices:** OPTICATH® Oximetry Catheter (K820674)
CVP Polyurethane Catheter (K961552)
- PreSep Central Venous Oximetry Catheter
(Edwards Lifesciences) (K053609)
- 6. Manufacturer and Establishment Registration Number:**
- | Manufacturer Site: | Sterilization Site: |
|--|--|
| ICU Medical (UTAH), Inc.
4455 Atherton Drive
Salt Lake City, UT 84123
Establishment Registration #: 1713468 | Isomedix Operations, Inc., Steris Corporation
9120 South 150 East
Sandy, UT 84070
Establishment Registration #: 1720929 |
| | Isomedix Operations, Inc., Steris Corporation
7685 St. Andrews Ave.
San Diego, CA 92154
Establishment Registration #: 2032112 |
- 7. Performance Standards:**
No performance standards have been established under Section 514 of the Food, Drug, and Cosmetic Act for Pressure Monitoring Devices. Cardiovascular Devices are regulated within 21 CFR 870.1230.
- 8. Intended Use / Indications for Use:**
The OPTICATH® Central Venous Oximetry Catheter is indicated for central venous pressure monitoring, drug and fluid administration, vascular access, venous blood sampling and the continuous in vivo measurement of the oxyhemoglobin saturation of blood in the central venous system (ScvO₂) for monitoring hemodynamic status during metabolic, respiratory, cardiovascular, and/or other physiological system(s) compromise in accordance with hospital protocols or current Clinical Standards of Practice.. The OPTICATH® Central Venous Oximetry Catheter is intended for one-time use.

The intended use is the same as for the predicate devices.

9. Proposed Device Description:

The OPTICATH® Central Venous Oximetry Catheter is a disposable single use central venous catheter with integrated fiber optics for measurement of blood oxyhemoglobin levels. It is compatible with existing Oximetrix 3, Q2 or Q2 Plus SO₂ monitors and SvO₂ modules manufactured by Philips, GE Medical and Spacelabs. The Central Venous Oximetry – Integrated Catheter is a component within a Hospira Central Venous Catheter (CVC) kit.

10. Summary of Substantial Equivalence

The OPTICATH® Central Venous Oximetry Catheter is substantially equivalent to the predicate OPTICATH® Oximetry Catheter, K820674 and Central Venous Catheter K961552 with respect to the following characteristics:

Similarities:

- 1) The OPTICATH® Central Venous Oximetry Catheter and predicates are intended for measuring central venous oxygen saturation, central venous pressure monitoring, drug and fluid administration, vascular access and venous blood sampling. The device is provided as non-pyrogenic and sterile and is intended for one-time use.
- 2) The OPTICATH® Central Venous Oximetry Catheter has 4 lumens and is 8 French where the CVP Polyurethane predicate has 2 or 3 lumens and is 7 French and the Opticath Oximetry Catheter has 5 lumens and is 7.5 or 8 French.
- 3) The technology and operating principles are the same.
- 4) The catheters are packaged within Central Venous Catheter Kit.
- 5) The materials of construction are the same.
- 6) The method of sterilization is the same as the OPTICATH® Oximetry Catheter.

Differences:

- 1) The OPTICATH® Central Venous Oximetry Catheter is 8 French where as the CVP Polyurethane predicate catheters are 7 French.
- 2) The method of sterilization is different from the CVP Polyurethane catheter.

11. Statement of Safety and Effectiveness

The subject and predicate devices are similar in design, materials of construction, components, intended use, labeling and manufacturing processes. The proposed modifications have been evaluated using bench testing as well as *in-vivo* non-clinical studies of which the results met the acceptance criteria and do not raise new issues of safety and/or effectiveness. Therefore, the OPTICATH® Central Venous Oximetry Catheter is substantially equivalent to the predicate Oximetry Catheter and the Central Venous Pressure Catheters.

The claim for substantial equivalence is supported by the information provided in the 510(k) submission.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 5 2006

Hospira, Inc.
c/o Ms. Nichol R. Wilding
Manager Global Device Regulatory Affairs
275 N. Field Drive H2-2
Lake Forest, IL 60045

Re: K061585
Trade Name: OPTICATH® Central Venous Oximetry Catheter
Regulation Number: 21 CFR 870.1230
Regulation Name: Fiberoptic oximetry catheter
Regulatory Class: Class II (two)
Product Code: DQE
Dated: August 30, 2006
Received: September 11, 2006

Dear Ms. Wilding:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

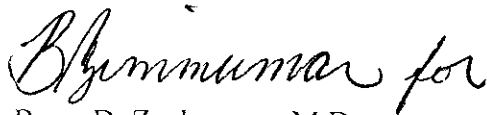
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Bram D. Zuckerman for".

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) K061585

Device Name: OPTICATH® Central Venous Oximetry Catheter

Indications for Use:

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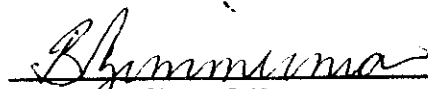
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K061585